



**B&C CONSORTIA
MANAGEMENT**

THE ETHYLENE OXIDE STERILIZATION ASSOCIATION, INC. (EOSA)

**GENERAL MEMBERSHIP MEETING
Baltimore, Maryland
October 24, 2018**

Jake Vandevort
B&C® Consortia Management
Washington, D.C.
www.bc-cm.com

WELCOME AND INTRODUCTIONS



ANTITRUST REMINDER

- Overview and reminder of the B&C® Consortia Management, L.L.C. (BCCM) antitrust policy for all conference calls and meetings
 - Please refer to the handout

AGENDA

- Administrative Matters
- Overview of Integrated Risk Information System (IRIS) and Advocacy Work
- Feature Presentation -- Exposure Modelling
- Environmental, Health, and Safety (EH&S) Committee Report
- State Legislative and Regulatory Matters
- International Regulatory Matters
- American Conference of Governmental Industrial Hygienists (ACGIH)
- EOSA Technical Conference
- Business Matters
- Closing

ADMINISTRATIVE MATTERS

- Approval of the March 18, 2018, Minutes
- Antitrust Reminder

APPROVAL OF DRAFT MINUTES

- March 18, 2018, Draft Minutes
- Approved minutes will be prepared in final and uploaded to the members' only website
- Draft minutes from today's meeting will be available by **October 30, 2018**

FEDERAL EMISSIONS REPORTS

- Updates Regarding the U.S. Environmental Protection Agency's (EPA) Integrated Risk Information System (IRIS) Assessment for Ethylene Oxide (EO)
- 2014 National Air Toxics Assessment (NATA) Update

FEATURE PRESENTATION

- Dr. Abby Li, Exponent
- Dr. Ken Bogen, Exponent
 - Exposure Modelling and EPA's IRIS Assessment for EO -- Opportunities and Next Steps

EH&S COMMITTEE

- Report of Today's Meeting
- Ongoing Initiatives
- Future/Potential Initiatives

EH&S -- ONGOING ACTIVITIES

- Recommended and Generally Accepted Good Engineering Practices (RAGAGEP)
- Review and Monitoring of State Regulatory Activities
- EO 101 Webinar

FUTURE/POTENTIAL TOPICS

- Development of Educational and Training Materials and/or Programs
- Economic Impact Analysis of the EPA IRIS Assessment
- Compilation of Federal Regulations Application to the U.S. EO Sterilization Industry
- Additional Webinars and Seminars

STATE MATTERS

- Texas Commission on Environmental Quality (TCEQ)
- Illinois
- California Safer Consumer Products Regulations (SCPR)
- Other State Regulatory Activities

OVERVIEW OF STATE REGULATORY MATTERS

- Some states are beginning to review benchmark concentrations and screening levels for ethylene oxide (EO) based on the U.S. Environmental Protection Agency's (EPA) Integrated Risk Information System (IRIS) Assessment
 - Michigan
 - Complete
 - Oregon
 - Complete
 - Texas
 - In Progress

ODEQ

- Updated the Ambient Benchmark Concentration (ABC) for EO from $0.01 \mu\text{g}/\text{m}^3$ to $0.0003 \mu\text{g}/\text{m}^3$
 - Previous value based on the 1987 California Office of Environmental Health Hazard Assessment (OEHHA) unit risk estimate of 8.8×10^{-5} per $\mu\text{g}/\text{m}^3$
 - New value based on the IRIS unit risk estimate of 3×10^{-3} per $\mu\text{g}/\text{m}^3$

TCEQ

- Working to develop a proposed Development Support Document (DSD) for EO
 - Effects Screening Level
 - Current Short-Term value is 20 ppb; Long-Term value is 2 ppb
 - Inhalation Reference Value
 - Inhalation Unit Risk Factor
- Timeline for publication is not yet available
- Stakeholders will have 90 days to comment

CALIFORNIA SCPR

- EO is a Candidate Chemical
- Priority Product Work Plan does not specifically reference EO
 - EOSA will continue to monitor and report on developments

OTHER STATE REGULATORY ACTIVITIES

- EOSA is monitoring other states for activity similar to Oregon, Michigan, and Texas
 - No other regulatory activities are currently in progress
 - A state-by-state matrix has been developed and will be refined and made available on the members' only website following review by the EH&S Committee

INTERNATIONAL REGULATORY MATTERS

- Residual Issues in Europe
- International Organization for Standardization (ISO)
- European Union (EU) Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)

RESIDUAL ISSUES IN EUROPE

- No recent activity regarding the use of EO on neonates
- EOSA has discussed opportunities for engagement with the Association for the Advancement of Medical Instrumentation (AAMI)
 - Many meetings are open to the public with the ability to listen, but not engage.

ISO

■ Update

- EOSA will continue to monitor this matter and report on new developments

REACH

- Maltese Presidency and European Parliament reached agreement on a new directive intended to protect workers from exposure to carcinogens or mutagens in the workplace
 - Proposal to set exposure limits for carcinogens, including EO
 - EO meets the criteria for classification as carcinogenic (category 1B)
 - It is possible to set a limit value based on available data
 - Scientific Committee on Occupational Exposure Limits (SCOEL) has identified the possibility of significant update through the skin

ACGIH

- EO has been placed on the Tier II Threshold Limit Value (TLV) Committee Under Study list
 - ACGIH will not move forward with a Notice of Intended Change (NIC) in **2019**
 - Can expect EO will remain on the Under Study list next year

EOSA TECHNICAL CONFERENCE

- Date and Location
- Updates on Planning, Registration, and Sponsorship
- Next Steps
- Discussion

DATE AND LOCATION

CONFERENCE OVERVIEW AND UPDATE

- To be scheduled in **September 2019** in either Salt Lake City or Park City, Utah
 - Single track technical sessions
 - Four days of sessions, including training and overviews
 - Will include the EOSA general membership meeting
 - Goal is to have approximately 125 attendees
 - Initial thought is to schedule a biennial conference
- EOSA has retained TLG to assist with meeting management
 - Currently sourcing venues and available dates
 - Will assist with all venue needs and onsite support

CONFERENCE OVERVIEW AND UPDATE

- EOSA is currently developing technical sessions, the conference budget, and identifying promotional needs and opportunities
 - Questionnaires and surveys will be provided to the membership
 - Marketing and promotion will begin once a contract is signed with a venue

NEXT STEPS

- Select the Host Venue
- Complete Session Development
- Set Budget and Registration Fees
- Develop Sponsorship Program
- Initiate Promotion
- Open Registration

BUSINESS MATTERS

- Membership Report
- Financial Report
- Executive Committee Report
- Membership Poll
- Next Membership Meeting
- Elections for EOSA President and Treasurer
- Summary of Action Items

MEMBERSHIP AND RECRUITMENT

- 41 Members
 - 24 General Members
 - 9 Associate Members
 - 8 International Members

MEMBERSHIP ROSTER

General Members

- | | |
|--|---|
| <ul style="list-style-type: none">• 3M• Alcon Research, Ltd.• Andersen Products• ARC Specialty Products• B. Braun Medical• Becton Dickinson• Consulting and Technical Services• Cook Incorporated• Cosmed Group• C. R. Bard• Elite Spice• ETC Sterilization Systems | <ul style="list-style-type: none">• Johnson & Johnson• Medline Industries, Inc.• Medtronic• Mesa Laboratories• Midwest Sterilization Corporation• PAMA Manufacturing• Sterigenics International• Sterilization Services• Sterilization, Validation, and Consulting• STERIS• Terumo BCT Sterilization Services• Viant Medical |
|--|---|

MEMBERSHIP ROSTER

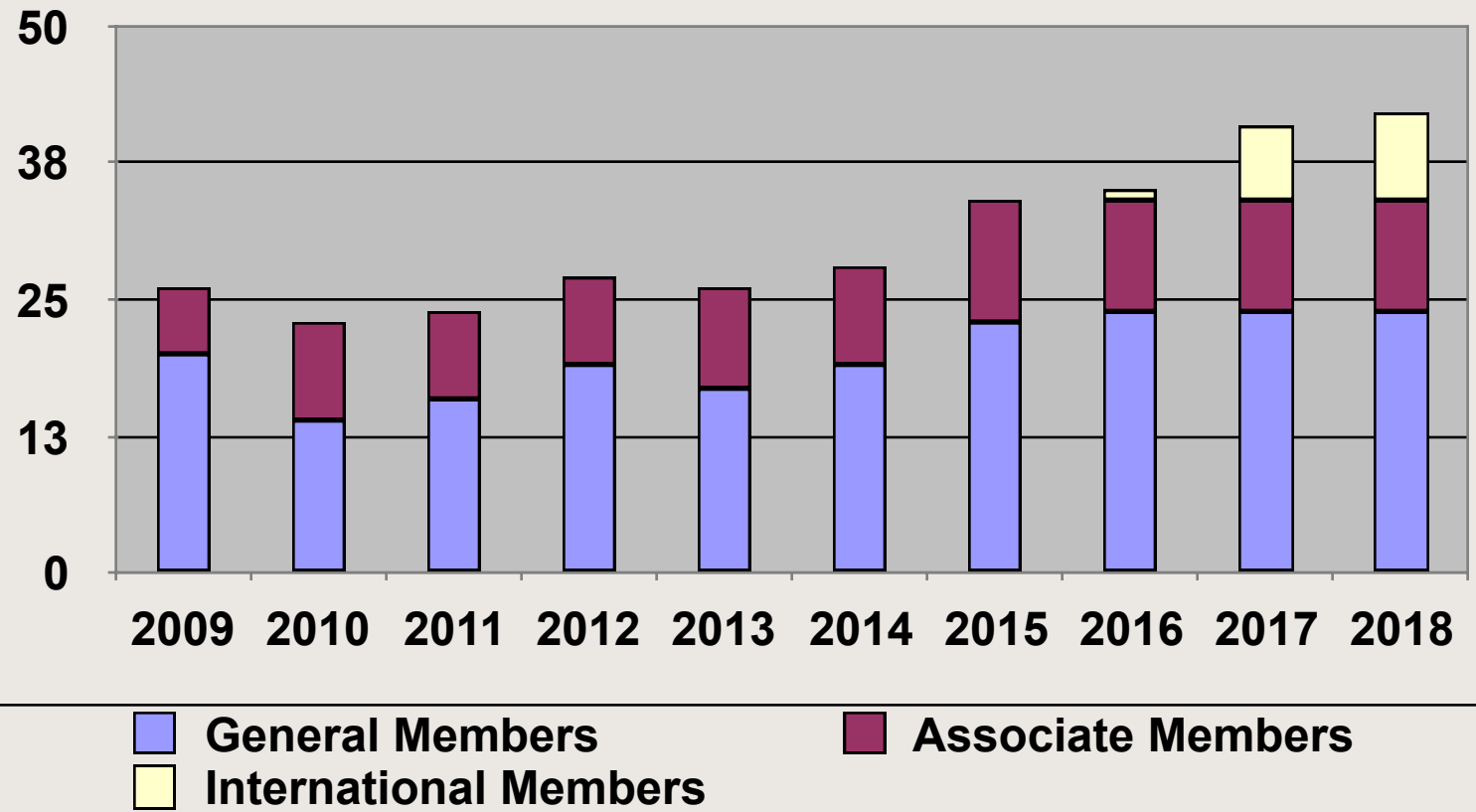
Associate Members

- | | |
|---|---|
| <ul style="list-style-type: none"> • Advanced Air Technologies • Cardinal Health • Carus Corporation • Coastline Chemical, Inc. • Konnexis | <ul style="list-style-type: none"> • Opulus • Primus Builders • Sensor Electronics Corporation • Vacudyne |
|---|---|

International Members

- | | |
|---|---|
| <ul style="list-style-type: none"> • Emerald Nonwovens • LESNI • Microtrol Sterilisation Services • Philips Volcano Corporation | <ul style="list-style-type: none"> • STEREO Corporation • Sterimed, S.A. • Steritech • Taiwan Advanced Sterilization Technology |
|---|---|

MEMBERSHIP HISTORY



FINANCIAL REPORT

- As of October 24, 2018 -- please see handout for full budget

| Budget Item | Budget | 10-24-2018 | Year-End Projection |
|-------------------------------|-----------|------------|---------------------|
| Membership Dues & Assessments | \$157,250 | \$157,250 | \$224,250 |
| Opening Balance | \$ 97,983 | \$ 97,983 | \$ 97,983 |
| Registration Fees | \$ 20,000 | \$ 11,500 | \$ 17,800 |
| Total Funding | \$275,233 | \$266,733 | \$340,033 |
| Expenses | \$178,500 | \$203,379 | \$338,105 |
| Available Balance | \$ 96,733 | \$ 63,354 | \$ 1,928 |

FINANCIAL REPORT

- The EOSA Board of Directors approved a one-time special assessment of \$142,000
 - \$67,000 in 2018; and
 - \$75,000 in **January 2019**
- Assessment will fund:
 - Exposure modelling work to provide a defensible alternative to the IRIS assessment; and
 - Emerging state regulatory and legislative activities

EXECUTIVE COMMITTEE REPORT

■ Report by Jonathan Bull

REVISIONS TO BYLAWS

- Executive Committee is reviewing proposed revisions to the EOSA bylaws
 - Membership definitions and categories
 - Preparation and review of communications
 - General clean-up and review
- Proposed revisions will be circulated to the membership for review, comment, and approval

NEXT MEMBERSHIP MEETING

- Tentatively scheduled for **Wednesday, October 24, 2018**
 - Hyatt Regency Baltimore Inner Harbor
 - EOSA will confirm the date following communication with AAMI regarding its schedule
- Officer Elections

THANK YOU

**JAKE VANDEVORT
B&C® CONSORTIA MANAGEMENT,
L.L.C.
2200 Pennsylvania Avenue, N.W.
Suite 100W
Washington, D.C. 20037
jvandevort@bc-cm.com
www.bc-cm.com**